

WO 2004/108753

PCT/AU2004/000775

## WHAT IS CLAIMED IS:

1. Use of at least one set of peptides in the preparation of a medicament for modulating an immune response, wherein individual peptides of a respective set comprise different portions of an amino acid sequence corresponding to a single polypeptide of interest and display partial sequence identity or similarity to at least one other peptide of the same set of peptides.
2. A use according to claim 1, wherein at least 2 sets of peptides are employed, and wherein peptide sequences in each set are derived from a distinct polypeptide of interest.
3. A use according to claim 1, wherein at least 3 sets of peptides are employed, and wherein peptide sequences in each set are derived from a distinct polypeptide of interest.
4. A use according to claim 1, wherein the partial sequence identity or similarity is contained at one or both ends of an individual peptide.
5. A use according to claim 4, wherein at least 4 contiguous amino acid residues are contained at one or both of these ends whose sequence is identical or similar to an amino acid sequence contained within at least one other of the peptides.
6. A use according to claim 1, wherein the peptide is at least 6 amino acid residues in length.
7. A use according to claim 1, wherein the peptide is no more than about 500 amino acid residues in length.
8. A use according to claim 1, wherein the length of the peptides is selected to enhance the production of a cytolytic T lymphocyte response.
9. A use according to claim 8, wherein the length of the peptides is from about 8 to about 10 amino acid residues.
10. A use according to claim 1, wherein the length of the peptides is selected to enhance the production of a T helper lymphocyte response.
11. A use according to claim 10, wherein the length of the peptides is from about 12 to about 20 amino acid residues.
12. A use according to claim 1, wherein the peptide sequences are derived from at least about 30% of the sequence corresponding to the polypeptide of interest.
13. A use according to claim 1, wherein the peptide sequences are derived from at least about 90% of the sequence corresponding to the polypeptide of interest.
14. A use according to claim 1, wherein the polypeptide of interest is an antigen selected from a protein antigen, an antigen expressed by cancer cells, a particulate antigen, an alloantigen, an autoantigen or an allergen, or an immune complex.
15. A use according to claim 1, wherein the polypeptide of interest is a disease- or condition-associated polypeptide.

WO 2004/108753

PCT/AU2004/000775

16. A use according to claim 15, wherein the disease- or condition-associated polypeptide is a polypeptide produced by a pathogenic organism or a cancer.

17. A use according to claim 15, wherein the disease- or condition-associated polypeptide is produced by a of pathogenic organism selected from yeast, viruses, bacteria, helminths, protozoans and mycoplasmas.

18. A use according to claim 15, wherein the disease- or condition-associated polypeptide is produced by a cancer selected from melanoma, lung cancer, breast cancer, cervical cancer, prostate cancer, colon cancer, pancreatic cancer, stomach cancer, bladder cancer, kidney cancer, post transplant lymphoproliferative disease (PTLD) and Hodgkin's Lymphoma.

19. An antigen-presenting cell or its precursor which has been contacted with at least one set of peptides for a time and under conditions sufficient for the peptides or processed forms thereof to be presented by the antigen-presenting cell or by its precursor, wherein individual peptides of a respective set comprise different portions of an amino acid sequence corresponding to a single polypeptide of interest and display partial sequence identity or similarity to at least one other peptide of the same set of peptides.

20. A population of antigen-presenting cells or their precursors which have been contacted with at least one set of peptides for a time and under conditions sufficient for the peptides or processed forms thereof to be presented by the antigen-presenting cells or by their precursors, wherein individual peptides of a respective set comprise different portions of an amino acid sequence corresponding to a single polypeptide of interest and display partial sequence identity or similarity to at least one other peptide of the same set of peptides.

21. A process for producing antigen-presenting cells for modulating an immune response to a polypeptide of interest, the process comprising contacting antigen-presenting cells or their precursors with at least one set of peptides for a time and under conditions sufficient for the peptides or processed form thereof to be presented by the antigen-presenting cells or by their precursors, wherein individual peptides of a respective set comprise different portions of an amino acid sequence corresponding to a single polypeptide of interest and display partial sequence identity or similarity to at least one other peptide of the same set of peptides.

22. A process according to claim 21, further comprising culturing for a time and under conditions sufficient to differentiate antigen-presenting cells from the precursors.

23. A process according to claim 21, wherein the or each set of peptides is contacted with substantially purified antigen-presenting cells or their precursors.

24. A process according to claim 21, wherein the or each set of peptides is contacted with a heterogeneous population of antigen-presenting cells or their precursors.

25. A process according to claim 22, wherein the heterogenous pool of cells is selected from blood or peripheral blood mononuclear cells.

WO 2004/108753

PCT/AU2004/000775

26. A process according to claim 21, wherein the antigen-presenting cells or their precursors are selected from monocytes, macrophages, cells of myeloid lineage, B cells, dendritic cells or Langerhans cells.

27. A process according to claim 21, wherein the or each set of peptides is contacted with an uncultured population of antigen-presenting cells or their precursors.

28. A process according to claim 27, wherein the population is homogenous.

29. A process according to claim 27, wherein the population is heterogeneous.

30. A process according to claim 27, wherein the population is a heterogeneous population selected from whole blood, fresh blood, or fractions thereof selected from peripheral blood mononuclear cells, buffy coat fractions of whole blood, packed red cells, irradiated blood, dendritic cells, monocytes, macrophages, neutrophils, lymphocytes, natural killer cells or natural killer T cells.

31. A method for producing antigen-specific lymphocytes, the method comprising contacting a population of lymphocytes, or their precursors, with the population of antigen-presenting cells or their precursors according to claim 19 for a time and under conditions sufficient to produce antigen-specific lymphocytes that modulate an immune response to at least one of the polypeptides of interest.

32. A composition comprising at least one set of peptides and a pharmaceutically acceptable carrier and/or diluent, wherein individual peptides of a respective set comprise different portions of an amino acid sequence corresponding to a single polypeptide of interest and display partial sequence identity or similarity to at least one other peptide of the same set of peptides.

33. A composition according to claim 32, further comprising an adjuvant or a compound that stabilises the peptides against degradation by host enzymes.

34. A composition comprising an antigen-presenting cell or its precursor according to claim 19, or a population antigen-presenting cells or their precursors according to claim 20, and a pharmaceutically acceptable carrier and/or diluent.

35. A composition according to claim 34, further comprising an adjuvant.

36. A composition comprising antigen-specific lymphocytes produced according to the of claim 31, and a pharmaceutically acceptable carrier and/or diluent.

37. A composition according to claim 36, further comprising an adjuvant.

38. A method for modulating an immune response to a polypeptide of interest, comprising administering to a patient in need of such treatment at least one set of peptides for a time and under conditions sufficient to modulate the immune response, wherein individual peptides of a respective set comprise different portions of an amino acid sequence corresponding to a single polypeptide of interest and display partial sequence identity or similarity to at least one other peptide of the same set of peptides.

WO 2004/108753

PCT/AU2004/000775

39. A method for modulating an immune response to a polypeptide of interest, comprising administering to a patient in need of such treatment a population of antigen-presenting cells according to claim 20 for a time and under conditions sufficient to modulate the immune response.

40. A method for modulating an immune response to a polypeptide of interest, comprising administering to a patient in need of such treatment antigen-specific lymphocytes produced according to the of claim 31 for a time and under conditions sufficient to modulate the immune response.

41. A method for treatment and/or prophylaxis of a disease or condition associated with the presence of a polypeptide of interest, comprising administering to a patient in need of such treatment or prophylaxis an effective amount of at least one set of peptides, wherein individual peptides of a respective set comprise different portions of an amino acid sequence corresponding to a single polypeptide of interest and display partial sequence identity or similarity to at least one other peptide of the same set of peptides.

42. A method for treatment and/or prophylaxis of a disease or condition associated with the presence of a polypeptide of interest, comprising administering to a patient in need of such treatment or prophylaxis an effective amount of a population of antigen-presenting cells according to claim 20.

43. A method for treatment and/or prophylaxis of a disease or condition associated with the presence of a polypeptide of interest, comprising administering to a patient in need of such treatment or prophylaxis an effective amount of antigen-specific lymphocytes produced according to the of claim 31.

44. A composition of matter for modulating an immune response in a subject to a target antigen, the composition comprising uncultured antigen-presenting cells or their precursors, which have not been subjected to activating conditions, and which have been contacted with an antigen corresponding to the target antigen for a time and under conditions sufficient to express a processed or modified form of the antigen for presentation to the subject's immune system.

45. A composition according to claim 44, wherein the uncultured antigen-presenting cells or their precursors are contacted with the antigen from about 1 minute to about 5 days.

46. A composition according to claim 44, wherein the uncultured antigen-presenting cells or their precursors are selected from whole blood, fresh blood, or fractions thereof.

47. A composition according to claim 46, wherein fractions are selected from peripheral blood mononuclear cells, buffy coat fractions of whole blood, packed red cells, irradiated blood, dendritic cells, monocytes, macrophages, neutrophils, lymphocytes, natural killer cells and natural killer T cells.

48. A composition according to claim 44, wherein the antigen corresponding to the target antigen is selected from: nucleic acids; peptides; hormones; whole protein antigens; cellular material; particulate matter selected from cell debris, apoptotic cells, lipid aggregates, membranous vehicles,

WO 2004/108753

PCT/AU2004/000775

microspheres, heat aggregated proteins, virosomes, virus-like particles; and whole organisms selected from bacteria, mycobacteria, viruses, fungi, protozoa or parts thereof.

49. A composition according to claim 44, wherein the antigen is selected from a proteinaceous molecule or a nucleic acid molecule.

50. A composition according to claim 44, wherein the uncultured cells are contacted with at two or more antigens.

51. A composition according to claim 50, wherein the antigens are in a form selected from overlapping peptides, non-overlapping peptides, one or more polynucleotides from which overlapping peptides are expressible or one or more polynucleotides from which non-overlapping peptides are expressible.

52. Use of uncultured antigen-presenting cells or their precursors in the preparation of a medicament for the treatment of a disease or condition in a subject, which disease or condition is associated with the presence or aberrant expression of a target antigen, wherein the antigen-presenting cells or their precursors have not been subjected to activating conditions but have been contacted with an antigen that corresponds to the target antigen for a time and under conditions sufficient to express a processed or modified form of the antigen for presentation to the subject's immune system.